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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/583,842

06/22/2006

Pankaj Khapra

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EXAMINER

VU, JAKE MINH

ART UNIT

PAPER NUMBER

1618

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DELIVERY MODE

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/583,842	Applicant(s) KHAPRA ET AL.	
	Examiner JAKE M. VU	Art Unit 1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 March 2010.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 28-34 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 28-34 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>9/13/06</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Receipt is acknowledged of Applicant's Restriction Requirement Response and Amendment filed on 03/11/2010; and Information Disclosure Statement filed on 09/13/2006.

- Claims 1-27 have been cancelled.
- Claims 28-34 have been added.
- Claims 28-34 are pending in the instant application.

Priority

Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 28-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over CHO (US 6,709,676) in view of DIETRICH et al (US 7,175,854) and FAOUR et al (US 6,605,302).

Applicant's claims are directed to a composition comprising of: desloratadine; meglumine; and an antioxidant, such as butylated hydroxytoluene; and a pharmaceutically acceptable excipient.

CHO teaches a composition comprised of: desloratadine (see col. 4, line 52-58), which is an antihistamine drug; a basic salt (see col. 4, line 60); an antioxidant (see col. 4, line 65); and a pharmaceutically acceptable excipient (see abstract). Additional disclosure includes: excipients that caused discoloration and instability of desloratadine include acidic excipients having a pH of less than 7, which would read that desloratadine is an acid-labile drug.

CHO does not specifically teach using meglumine or a specific antioxidant, such as butylated hydroxytoluene.

DIETRICH teaches the addition of basic compounds, such as meglumine and basic salts, results in stable preparation and prevents possible discolorations of acid-labile active ingredients (see col. 30, line 49-58).

FAOUR teaches a composition comprised of an antihistamine drug, such as loratadine (see abstract) and an antioxidant, such as butylated hydroxytoluene to prevent deterioration of the composition (see col. 11, line 58-63).

It would have been obvious to the person of ordinary skill in the art at the time the invention was made to incorporate meglumine into CHO's desloratadine composition. The person of ordinary skill in the art would have been motivated to make those modifications, because the meglumine would result in a stable preparation and prevents possible discolorations of acid-labile desloratadine drug, and reasonably would have

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expected success because both reference dealt with the same field of endeavor, such as pharmaceutical drugs.

It would have been obvious to the person of ordinary skill in the art at the time the invention was made to incorporate butylated hydroxytoluene into CHO's composition. The person of ordinary skill in the art would have been motivated to make those modifications, because the butylated hydroxytoluene would prevent deterioration of the drug composition, and reasonably would have expected success because CHO teaches using antioxidant.

The references do not specifically teach adding the ingredients in the amounts claimed by Applicant. The amount of a specific ingredient in a composition is clearly a result effective parameter that a person of ordinary skill in the art would routinely optimize. Optimization of parameters is a routine practice that would be obvious for a person of ordinary skill in the art to employ and reasonably would expect success. It would have been customary for an artisan of ordinary skill to determine the optimal amount of each ingredient to add in order to best achieve the desired results, such as the minimum amount necessary to prevent deterioration of the drug. Thus, absent some demonstration of unexpected results from the claimed parameters, this optimization of ingredient amount would have been obvious at the time of Applicant's invention.

Note, the limitation of "N-formyl impurity of desloratadine" and "does not undergo discoloration" are inherent chemical and physical properties of the composition;

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therefore, the references would inherently meet these limitations, since the references have the same ingredients as claimed by Applicant.

Telephonic Inquiries

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JAKE M. VU whose telephone number is (571)272-8148. The examiner can normally be reached on Mon-Tue and Thu-Fri 8:30AM-5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Jake M. Vu/
Primary Examiner, Art Unit 1618